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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,173	07/24/2003	Jeyascelan Raju	MPI98-105P1RCP2DV1M	1880

30405 7590 09/22/2004

MILLENNIUM PHARMACEUTICALS, INC.
40 Landsdowne Street
CAMBRIDGE, MA 02139

EXAMINER

MONSHIPOURI, MARYAM

ART UNIT PAPER NUMBER

1652

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/626,173

Applicant(s)

RAJU, JEYASEELAN

Examiner

Maryam Monshipouri

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/24/03</u> . | 6) <input checked="" type="checkbox"/> Other: <u>sequence alignment</u> . |

Applicant's response to restriction requirement filed 6/17/2004 is acknowledged. Applicant elected Group I invention directed to claims 1-12 (methods of use of SEQ ID NO:2) without traverse.

DETAILED ACTION

Claims 1-12 are under examination on the merits.

Information Disclosure statement

In pages 4-9 of the IDS filed 7/24/2003 applicant is citing a series of Genbank accession Numbers and Blast searches with no associated date of entry or submission, and are thereby incomplete. The examiner of record searched for said references in parent cases but unfortunately was unsuccessful. If applicant is interested in incorporating said references in his/her IDS, it is requested that he/she resubmit said references with corresponding dates or possibly filling the corresponding date of each reference in the 1449 form in response to this office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

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had possession of the claimed invention. In pages 16-17 of the specification, it is noted that the applicants have deposited the organisms (see claim 1(a)) under the terms of Budapest treaty but there is no indication in the specification as to the public availability. Since the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of the patent, would satisfy the deposit requirement made herein. Claims 2-12 are merely rejected for depending from rejected claim 1.

Claims 1-2, and 7-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The examiner looked for support of hybridization conditions recited in claim 1(b) in the specification and could not find any. Hence, for examination purposes said hybridization and wash conditions are considered to be **new matter**. Applicant is advised to either refer the examiner to exact location wherein said hybridization and wash conditions are recited in the specification or possibly delete said conditions from claim 1. Claims 2-3 and 7-12 are merely rejected for depending from a rejected base claim.

Claims 1-2 and 6-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of identifying kinase activity of SEQ

ID NO:2 and its claimed variants, does not reasonably provide enablement for any activity of said products beyond kinase activity. In claim 1 applicant does not specify the exact activity (activities) of polypeptides which are used in claimed methods.

The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2n 1400 (Fed. Cir. 1988) are: 1) the quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breadth of the claims.

The specification fails to teach any other assay methods beyond those of a kinase. No examples of assay methods of other SEQ ID NO:2 activities are provided either. Prior art is unpredictable about how to assay for activities beyond kinase activity of claimed polypeptides, such that could be exploited in claimed invention.

Therefore due to lack of sufficient teachings and examples in the specification and due to unpredictability of prior art as how to assay for other activities of claimed polypeptides one of skill in the art has to go through the burden of undue experimentation in order to screen for modulators of other activities of claimed polypeptides and as such the claim goes beyond the scope of the specification. Claims 2, and 6-12 are merely rejected for depending from rejected base claim 1.

Claims 1, 3-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

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invention. In Claim 1(e) applicant is claiming a methods of identifying modulators of “activity” of polypeptides consisting of 25 consecutive amino acids of SEQ ID NO:2.

The criteria for undue experimentation is cited above. The specification does not teach about activities of polypeptides consisting of 25 amino acids of SEQ ID NO:2. No examples of such activities are provided either. Prior art is totally unpredictable about what activities a polypeptides of 25 amino acids must have.

Therefore, due to lack of sufficient teachings and examples in the specification and due to unpredictability of prior art as to how to screen for activities of polypeptides consisting of at least 25 amino acids of any polypeptide including SEQ ID NO:2 of this invention one of skill in the art has to go thorough the burden of undue experimentation in order to practice the method as claimed. Claims 3-12 are merely rejected for depending from a rejected base claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Plowman et al., (WO200073469, 12/2000). As mentioned above, the examiner could not find support for the methods of use of polypeptides as claimed in claim 1(b) in the parent applications. Hence, the earliest filing date that current invention can benefit from is 7/24/2003 which is filing date of instant application. Based on this date Plowman

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teaches methods of identifying modulators (see pages 56 and 68 of the specification) of its kinase polypeptides that have 100% identity to SEQ ID NO:2 and are encoded by DNA molecules that can hybridize to SEQ ID NO:3 under conditions recited in claim 1(b) and 3. Since polypeptides of Plowman display 100% identity to those used in claim 1(b) Plowman methods inherently anticipate claims 4-12 of this invention.

No claims are allowed.

Allowable Subject Matter

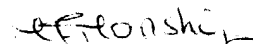
SEQ ID NO:2 is free of prior art. Further the prior art does not teach or suggest preparing such specifically claimed polypeptide. Hence said polypeptide is non-obvious. Since claimed amino acid sequence is both novel and non-obvious methods of use of said polypeptide as specifically claimed is also novel and non-obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 4:30 p.m. except for alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnanthapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Maryam Monshipouri Ph.D.

Primary Examiner

QY 1981 GGGCAATTCATTCGCTCATCTCAAGCCAGGCG/CGGGCAGCAGCATGCTTACCA 2040
 DB 1981 GGGCAATTCATTCGCTCATCTCAAGCCAGGCGCTGGGCGAGCAGCATGGCTTACCA 2040
 QY 2041 CACATCAGACCTCCCATTTGGCTATTCATTCCTCCAGCCCATATCTCTCTCATPAGA 2100
 DB 2041 CACATCAGACCTCCCATTTGGCTATTCATTCCTCCAGCCCATATCTCTCTCATPAGA 2100
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 DB 2101 GGGTGGAAACGATGCTCTGTAAGGAAGAACCCCAATTTCTGAAGTTGTCAATGA 2160
 QY 2161 GAGTCTCTGCAACATTTGAGCTGATGTCTCTGATCAAGTAAACAGAGTGGTCTTC 2220
 DB 2161 GAGTCTCTGCAACATTTGAGCTGATGTCTCTGATCAAGTAAACAGAGTGGTCTTC 2220
 QY 2221 TCACCT 2280
 DB 2221 TCACCT 2280
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 DB 2281 GCGACATTAAAGATGCTTCTGAAATGGAATATGCTCTAAATGCAAGTCTTATGCTGT 2340
 QY 2341 TTGTCCTCAAGTCTGAGCAATATCTCTCTCAAGTCTGCTTTTGAAGAGATGAAAGA 2400
 DB 2341 TTGTCCTCAAGTCTGAGCAATATCTCTCTCAAGTCTGCTTTTGAAGAGATGAAAGA 2400
 QY 2401 AGTCTCAATACACACCCATTTACCAATATGCTCTATGCCATGCCAGAGCTCATG 2460
 DB 2401 AGTCTCAATACACACCCATTTACCAATATGCTCTATGCCATGCCAGAGCTCATG 2460
 QY 2461 CATTTCATCTCTGCGCAATATGAGCAGCTTTGAGAGCAGCAGC 2505
 DB 2461 CATTTCATCTCTGCGCAATATGAGCAGCTTTGAGAGCAGCAGC 2505

RESULT 2

AAFA4702
 ID AAFA4702 standard; cDNA; 2508 BP.

AC AAFA4702;
 XX

DT 27-MAR-2001 (first entry)

DE Novel protein kinase cDNA, SEQ ID NO: 83.

XX Human; mouse; protein kinase; antiarthritic; antisclerotic; osteopathic;
 XX immunosuppressive; cardiac; renal; antiinflammatory; antiaslathmic;
 KW dermatological; antidiabetic; antifertility; gene therapy; vaccine;
 KW immune disorder; cardiovascular disease; neurodegenerative disease;
 KW cancer; autoimmune disorder; stroke; inflammatory bowel disease;
 KW inflammatory pelvic disease; multiple sclerosis; psoriasis; ss.

OS Homo sapiens.

XX WO200073469-A2.

XX PD 07-DEC-2000.

XX PF 26-MAY-2000; 2000WO-US014842.

XX PR 28-MAY-1999; 99US-0136503P.

XX PA (SUGEN-) SUGEN INC.

XX PI Plowman GD, Martinez R, Whyte D, Sudersanam S;

XX DR WPI; 2001-032161/04.

XX DR P-PsDB; AAB65674.

PT Nucleic acids encoding kinase polypeptides, useful for diagnosing and
 PT treating immune-related diseases and disorders, cardiovascular disease,

PT neurodegenerative diseases and/or cancers.
 XX Disclosure; Fig 2; 310pp; English.
 PS
 XX The present sequence encodes a novel protein kinase. The nucleic acids
 CC and the protein kinases they encode may be used in the treatment and
 CC diagnosis of diseases associated with inappropriate kinase expression
 CC such as immune-related diseases and disorders, cardiovascular disease,
 CC neurodegenerative diseases and/or cancers. The nucleic acids and
 CC complementary sequences may also be used as DNA probes in diagnostic
 CC assays. The kinase polypeptides may be used as antigens in the production
 CC of antibodies of kinase expression and activity. Anti-kinase antibodies
 CC and kinase antagonists may also be used to down regulate kinase
 CC expression and activity. Diseases related to kinase expression and
 CC activity include rheumatoid arthritis, atherosclerosis, autoimmune
 CC disorders, complications of organ transplantation, myocardial infarction,
 CC immune disorders, cardiomyopathies, strokes, renal failure, oxidative-
 CC stress related disorders, chronic inflammatory bowel disease, chronic
 CC inflammatory pelvic disease, multiple sclerosis, asthma, osteoarthritis,
 CC psoriasis, rhinitis, autoimmunity, diabetes, cancers and reproductive
 CC disorders
 XX
 SQ Sequence 2508 BP; 722 A; 532 C; 555 G; 699 T; 0 U; 0 Other;
 Query Match 100.0%; Score 2505; DB 4; Length 2508;
 Best Local Similarity 100.0%; Pred. No. 0;
 Matches 2505; Conservative 0; Mismatches 0; Indels 0; Gaps 0;
 QY 1 ATGGGAATTTATTAATCTAGACCAACCCAACTTGTAGTATGAAAGAAAAGTC 60
 DB 1 ATGGGAATTTATTAATCTAGACCAACCCAACTTGTAGTATGAAAGAAAAGTC 60
 QY 61 AGTGAATCATATGTTATTCACAAATAGAAAGATTGAAGATGACCTGCAGATCAAGAAAA 120
 DB 61 AGTGAATCATATGTTATTCACAAATAGAAAGATTGAAGATGACCTGCAGATCAAGAAAA 120
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 DB 121 GAACGACAGAACTAAGAAATATATTTGGCTCTGATGAAGACCTTCAGTAAGCAATT 180
 QY 181 AATTACCGCACTGAAATAGGGCTGTCTACTTCAATTATGTTGCAATTTGTGGAGCAG 240
 DB 181 AATTACCGCACTGAAATAGGGCTGTCTACTTCAATTATGTTGCAATTTGTGGAGCAG 240
 QY 241 AATACATATTCGAACCTTATGTTGAAGAGGCTCCGCCATCTCGACTGCAAGAAAT 300
 DB 241 AATACATATTCGAACCTTATGTTGAAGAGGCTCCGCCATCTCGACTGCAAGAAAT 300
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 DB 301 GGATTTACAGCTTGGCATTTAGCAATTTACAGATTAATGCAAGATTGATCATCTCTG 360
 QY 361 CTTACAGTGAAGCTGATATACAGAGGATGATACGGTGGCTACAGCCCTCCATATT 420
 DB 361 CTTACAGTGAAGCTGATATACAGAGGATGATACGGTGGCTACAGCCCTCCATATT 420
 QY 421 GCTACAAATAGCTGGCCACCTAGAGGCTGATGCTGTTGCAACATGAGCTATATTC 480
 DB 421 GCTACAAATAGCTGGCCACCTAGAGGCTGATGCTGTTGCAACATGAGCTATATTC 480
 QY 481 AATATTCAGAGTGAAGTTTTTTTCACTCCATTCGATATGCAAGGATGATGACATGAA 540
 DB 481 AATATTCAGAGTGAAGTTTTTTTCACTCCATTCGATATGCAAGGATGATGACATGAA 540
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 DB 541 CAGGTAATCGCTCTCTTTTGAATTTGGTCTGATGTAATGTAAGTGGTGAAGTTGA 600
 QY 601 GATGACCCCTCCACCTAGCATCTGCAAGAAAGATTCTGGAATATTTGCAAAACTTTGATG 660
 DB 601 GATGACCCCTCCACCTAGCATCTGCAAGAAAGATTCTGGAATATTTGCAAAACTTTGATG 660
 QY 661 GAAAGAGCAGCAAGAGATGTAATGCTCAGATATATGAAGCATTGCTCCACTCAT 720

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Db 661 GAAAGAGCAGCAAGAGATGTGATCTCAAGATTAAGAAACATGTCCTCATCT
Qy 721 TCTGTCGATTTGGACACCATGATAGTATAGTATGTCCTGCGCAAGATTTGAA
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Db 1861 ATGACAAAACACCTGGGAACCTCCGTTGATGAGCTCTGAGGGTTCAGCGATGAC
Qy 1921 CGGTACACATCAAGAGAGATGTTCTTCAAGTATGCTGATGCTGATGAGGAAATTC
Db 1921 CGGTACACATCAAGAGAGATGTTCTTCAAGTATGCTGATGCTGATGAGGAAATTC
Qy 1981 GGGGAATTTCAATTCGCTCATCTTCAAGCCAGCGCTGCGGACAGACATGCTTAC
Db 1981 GGGGAATTTCAATTCGCTCATCTTCAAGCCAGCGCTGCGGACAGACATGCTTAC
Qy 2041 CACATCAGACCTCCCATTTGGCTATTTCCATTCGCAAGCCATATCATCTGCTGATG
Db 2041 CACATCAGACCTCCCATTTGGCTATTTCCATTCGCAAGCCATATCATCTGCTGATG
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Qy 2221 TCACCTTCTCTCTCTCTCTCTCTCTCTCTCTCTCTCTCTCTCTCTCTCTCT
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Qy 2281 GCGCATTAAGAGAGTGTGATGATGATGATGATGATGATGATGATGATGATGATG
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Qy 2401 AGCTTCAATTAACACCCATTTGCAATTAATGATGATGATGATGATGATGATG
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Qy 2461 CATTTCATTTCTGCGGAATTAATGATGATGATGATGATGATGATGATGATG
Db 2461 CATTTCATTTCTGCGGAATTAATGATGATGATGATGATGATGATGATGATG

```

RESULT 3
 AAA47606 standard; cDNA; 3025 BP.
 ID AAA47606;
 AC AAA47606;
 XX
 XX 20-OCT-2000 (first entry)
 XX
 DE Human CARK (Cardiac related Ankyrin-Repeat Protein Kinase) cDNA.
 KW Cardiac related ankyrin repeat protein kinase; CARK; cytoskeleton;
 KW cardiac cell growth factor receptor; cell differentiation; modulator;
 KW regulator; detection; cellular proliferation; cardiovascular disorder;
 KW heart failure; hypertension; cancer; sarcoma; ds.
 XX
 OS Homo sapiens.
 XX
 XX
 FH Key Location/Qualifiers
 FT CDS 48..2555
 FT /tag= a
 FT /product= "Human CARK"
 XX